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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|--|-------------|-----------------------|----------------------------|------------------|
| 10/517,497 | 05/26/2005 | Fabienne Andrea Fulde | U 015529-5 | 7362 |
| 140 | 7590 | 06/25/2007 | | |
| LADAS & PARRY 26 WEST 61ST STREET NEW YORK, NY 10023 | | | EXAMINER QIAN, CELINE X | |
| | | | ART UNIT | PAPER NUMBER |
| | | | 1636 | |
| | | | MAIL DATE | DELIVERY MODE |
| | | | 06/25/2007 | PAPER |

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

| | | | |
|------------------------------|---|-------------------------------------|--|
| Office Action Summary | Application No. 10/517,497 | Applicant(s) FULDE ET AL. | |
| | Examiner Celine X. Qian Ph.D. | Art Unit 1636 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-36 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☐ Claim(s) ____ is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☒ Claim(s) 1-36 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. ____. |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date ____. | 6) <input type="checkbox"/> Other: ____. |

DETAILED ACTION

Claims 1-36 are pending in the application.

Election/Restrictions

Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group I, claim(s) 1-16, drawn to a screening method for compounds that have a modulating effect on cellular development or differentiation by cultivating cells harboring a promoter-reporter construct in a 3D micro-culture under conditions that mimic the natural in vivo environment or 2D culture on bioinductive material, contacting cells with a test compound and comparing the read out of the reporter construct.

Group II, claim(s) 17-20, drawn to a method of producing a transgenic animal comprising a promoter reporter construct and a transgenic animal produced thereof, and a method of using said animal, and a cell derived from said animal.

Group III, claims 21-26, drawn to a DNA construct comprising a reporter gene under the control of a human reporter, a cell or cell line comprising said construct.

Group IV, claim 27, drawn to a method of performing an assay with a cell line which comprises a reporter construct.

Group V, claim 28, drawn to a method of using a cell for the in vitro formation of tissue.

Group VI, claims 29-34, drawn to a method for testing whether a material has bioinductive characteristics by culturing cells harboring a promoter reporter construct on the material to be tested and comparing the read out to a control.

Group VII, claims 35 and 36, drawn to a method for quality control of cells cultivated in vitro by transfecting cells that have been cultured in vitro with a key marker promoter-reporter construct and cultivating said cells in a 3D culture, and detecting the reporter read out which is inductive for differentiated cells.

PCT Rule 13.2 requires that unity of invention exists only when the shared same or corresponding technical feature is a contribution over the prior art. The inventions listed as Groups I-VII do not relate to a single general inventive concept because they lack the same or corresponding special technical feature. The “special technical feature” of Group I is a cell comprising a promoter-reporter construct in culture *in vitro*, which is shown by Cho JY et al. (see IDS) to lack novelty or inventive step over the claimed cell, and does not make a contribution over the prior art. As such, this technical feature cannot link the invention as a whole to form a single general inventive concept under PCT Rule 13.1.

The invention of the remaining groups each has a unique technical feature not shared by the other groups. The special technical feature of Group II is a transgenic animal comprising promoter-reporter construct, which is not shared by the remaining groups. The special technical feature of Group III is a construct comprising a promoter and reporter construct, which is not share by the remaining groups. The special technical feature of Group IV is an assay for using a cell line that is transfected with a promoter reporter construct, which is not shared by the remaining groups. The special technical feature of Group V is a cell for formation of a tissue, which is not shared by the remaining group. The special technical feature of Group VI is a method for testing a bioinductive material by using cultured cells harboring a promoter reporter construct, which is not shared by the remaining groups. The special technical feature of Group VII is a method for quality control of cells cultivated *in vitro* by transfecting cells with a key marker promoter-reporter construct, which is not shared by the rest of the groups. Therefore, the unity of invention does not exit between the claims of Groups I-VII.

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Applicant is advised that the reply to this requirement to be complete must include (i) an election of a species or invention to be examined even though the requirement be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected invention.

The election of an invention or species may be made with or without traverse. To reserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse.

Should applicant traverse on the ground that the inventions or species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the inventions or species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C.103(a) of the other invention.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Celine X. Qian Ph.D. whose telephone number is 571-272-0777. The examiner can normally be reached on 9:30-6:00 M-F.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joe Woitach Ph.D. can be reached on 571-272-0739. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Celine X Qian Ph.D.
Examiner
Art Unit 1636

CELINE QIAN, PH.D.
PRIMARY EXAMINER

